UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,	:	
Plaintiff,	:	Civil Action No. 05-11805-NMG
v.	:	
RICHARD F. SELDEN,	:	
Defendant.	:	

STIPULATION OF UNDISPUTED FACTS

In lieu of a Rule 30(b)(6) deposition of the Securities and Exchange Commission ("SEC") by the person or persons most knowledgeable about the subjects referenced in paragraph 1 below, the SEC and Richard F. Selden ("Dr. Selden") hereby stipulate that the following facts are undisputed and admissible at the trial of this action:

1. On April 27, 2007, as part of preparing his defense, Dr. Selden noticed a May 21, 2007 deposition of the SEC pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, seeking testimony from the SEC on two topics:

(1) Overview of SEC/FDA coordination as it relates to this case including confirmation of materials provided by FDA to SEC.

(2) SEC guidance made available to issuers regarding disclosure of status of INDs/NDAs/BLAs with FDA/CBER/CDER.

2. "IND" stands for Investigational New Drug application, a form of FDA application used to obtain approval to conduct clinical trials for products.

3. "NDA" stands for New Drug Application, a form of FDA application used to obtain FDA approval to market a drug product in the United States.

4. "BLA" stands for Biologics License Application, a form of FDA application used to obtain FDA approval to market a biologic product in the United States.

5. "CBER" and "CDER" stand, respectively, for the Center For Biologics Evaluation And Research and the Center For Drug Evaluation And Research, two branches of the FDA involved in reviewing INDs, NDAs and/or BLAs.

(1) Overview of SEC/FDA coordination as it relates to this case including confirmation of materials provided by FDA to SEC

6. The SEC has no first-hand knowledge of the matters at issue in this case. All of its factual knowledge is contained in its non-privileged investigative file, which it began to assemble on or about October 3, 2002, and which it first made available to Dr. Selden on or about October 7, 2005.

7. FDA application materials (such as documents relating to INDs, NDAs and BLAs) typically contain confidential commercial information and, as a result, are not available to the public on request. See, e.g., 18 U.S.C. § 1905; 21 C.F.R. § 20.61.

8. The SEC confidentially asked the FDA for non-public documents and received from the FDA the documents it requested without delay and without the need of court process.

9. On October 22, 2002, approximately three weeks after the SEC began its investigation, and nearly three years before filing suit against Dr. Selden, the SEC sent a confidential letter to the FDA asking for the confidential provision of documents and other information. The SEC's letter requested, among other things, the "[i]dentification of and assistance from the FDA representatives that reviewed [TKT's] Replagal application and spoke with [TKT's] management." The FDA granted all of the SEC's requests.

10. On February 10, 2003, the SEC sent a second confidential request for documents to the FDA. The SEC's letter requested, among other things, "[d]ocuments and information reflecting communications and the substance thereof between FDA representatives and officers, employees or representatives of [TKT] relating to the application for approval for Replagal for the time period July 1, 2000 through the present." The FDA granted all of the SEC's requests.

11. The FDA provided documents in response to the SEC's requests on November 18, 2002, January 23, 2003, and May 28, 2003. The SEC represents that the following document identification number ranges constitute all of the documents that the SEC obtained from the FDA during the SEC's investigation:

FDA-193138573-00001-67
FDA-193138567-00001-16
FDA-193138562-00001-874

12. In response to the SEC's October 2002 and February 2003 requests, the FDA also provided the SEC with access to all FDA employees with potentially responsive documents or information. The SEC represents that the following constitute all interviews that the SEC conducted of FDA employees during the SEC's investigation:

November 14, 2002 interview of John Treacy
May 30, 2003 interview of Marc Walton

13. On June 25, 2003, the SEC requested sworn testimony from the FDA's Marc Walton. One day later, the FDA authorized the SEC's request. The SEC represents that the following constitute all sworn testimony that the SEC obtained from the FDA during the SEC's investigation:

July 22, 2003 testimony of Marc Walton

14. The following constitute all written communications between the SEC and the FDA relating to TKT or to Dr. Selden that were produced by the SEC to Dr. Selden in this action:

July 24, 2002 L. Ogram (FDA) letter to J. Riedler (SEC)
Aug. 19, 2002 J. Johnson (FDA) fax/letter to K. Hands/J. Riedler (SEC)
Oct. 22, 2002 K. Poverman (SEC) letter to L. Ogram (FDA)
Jan. 23, 2003 J. Treacy (FDA) fax/attach. to D. Butler (SEC)
Feb. 10, 2003 D. Bergers (SEC) fax cover/letter to L. Ogram (FDA)
May 15, 2003 D. Butler (SEC) fax cover/attachs. to M. Brill (FDA)
May 28, 2003 J. Davis (FDA) letter to D. Butler (SEC)
June 5, 2003 D. Butler (SEC) letter to P. Beckerman (FDA)
June 25, 2003 D. Bergers (SEC) letter to L. Ogram (FDA)
June 26, 2003 L. Ogram (FDA) letter to D. Bergers (SEC)

(2) SEC guidance made available to issuers regarding disclosure of status of INDs/NDAs/BLAs with FDA/CBER/CDER

15. There are various ways in which the SEC can provide guidance to issuers about how to make public disclosures. Among the various forms that this SEC guidance can take are the following:

Concept Releases
Frequently Asked Questions (FAQs)
Interpretive Releases
No-Action Letters
Policy Statements
Press Releases
Proposed Rules
Rules
Special Studies
Speeches and Testimony
Staff Legal Bulletins
Staff Letters
Telephone Interpretations

The following are examples of SEC guidance:

Examples of SEC Guidance

#	Guidance	Type
1.	"Securities Act Industry Guides" and "Exchange Act Industry Guides" (Undated) [Item 801, 17 C.F.R. §229.801; Item 802, 17 C.F.R. §229.802]	Industry Guides
2.	"Division of Corporation Finance Manual of Publicly Available Telephone Interpretations" (June 8, 2001)	Telephone Interpretation
3.	"Auditing Internal Control Over Financial Reporting" (Jun. 23, 2004; Revised Jul. 27, 2004)	PCAOB Staff Questions and Answers
4.	"Commission Statement about Management's Discussion and Analysis of Financial Condition and Results of Operations" (Jan. 23, 2002) [Rel. Nos. 33-8056; 34-45321; FR-61]	Interpretive Release
5.	"Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements" (Sept. 13, 2006) [Rel. No. SAB 108]	Accounting Bulletin
6.	"Management's Report on Internal Control Over Financial Reporting" (Dec. 27, 2006) [71 Fed. Reg. 77,635]	Proposed rule

16. During all times relevant to the SEC's claims in this action, including the period June 16, 2000 through the present, the SEC provided no guidance to issuers about how to make disclosure of the status of FDA applications or the results of clinical trials. For example, there have been no SEC guidelines, protocols, FAQs or any other types of advisories issued for the information or assistance of those making disclosures regarding status before the FDA or the results of clinical trials.

Dr. Selden hereby formally withdraws his April 27, 2007 Rule 30(b)(6) deposition notice on the SEC.

Dated: July 9, 2007
Boston, Massachusetts

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Justin J. Daniels, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on July 9, 2007.

Dated: July 9, 2007

/s/ Justin J. Daniels
Justin J. Daniels